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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,652	07/27/1999	CHARLES S. ZUKER	2307E-88610	5785

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/361,652	Applicant(s) ZUKER ET AL.	
	Examiner Michael Brannock	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8,34,35 and 61-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8,34,35 and 61-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>042406</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 4/24/06, have been entered in full.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Maintained Rejections:

Claims 1, 4-6, 8, 34, 35, 61-67 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth item 9 of Paper 12 (1/3/01).

Applicant argues that the notion that one of skill in the art would find the asserted utility credible has already been established by Dr. Zuker's Declaration and not yet rebutted by the Examiner. This argument has been fully considered but not deemed persuasive. Applicant is referred back to pages 3-5 of Paper 26 (11/26/02) wherein the Zuker Declaration is thoroughly discussed.

Applicant argues that the examiner has dismissed the Nelson et al. reference. This argument has been fully considered but not deemed persuasive. To the contrary, the Examiner discussed the Nelson reference as providing the evidence that the GPCR-B3 protein has a specific role in taste signal transduction, and that this is provided in the Nelson et al. paper but

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not in the instant specification. The skilled artisan would appreciate that Nelson et al. show that GPCR-B3 in combination with T1R3 could be used to assay for modulators of taste perception; however the instant specification does not point to such a combination.

Applicant argues that it is possible that GPCR-B3 could, alone, have a role in taste transduction. This argument has been fully considered but not deemed persuasive. Many things are possible but simply inviting an artisan to test various ideas to try to find a way to use the polypeptide does not provide for a substantial utility.

In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion.”

At the time of filing, the instant specification refers to a protein of as yet undetermined function or biological significance and thus is not refined and developed to a point where specific benefit exists in currently available form.

Claims 1, 4-6, 34, 35, 61-67 also stand rejected under 35 U.S.C. 112 first paragraph, as set forth in item 10 of Paper 12. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set

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forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation, as set forth previously.

Applicants' arguments regarding the 35 U.S.C. § 112 rejection as the corollary of the 35 U.S.C. § 101 rejection have been addressed above.

Additionally, the specification has failed to show how to get a polypeptide of SEQ ID NO: 1, 2, or 3 to bind glutamate, or any other ligand, or to induce GPCR activity. As set forth above Nelson et al. show that GPCR-B3 in combination with T1R1 could be used to assay for modulators of taste perception; however the instant specification does not point to such a combination. There is no record of the instant polypeptides either binding to glutamate or having any functional GPCR activity. As admitted by Applicant, the functional polypeptide referred to in the specification is a chimeric polypeptide wherein the extracellular domain of the murine MGluR1 receptor was required to make a functional GPCR and to bind glutamate.

The generalized methods pointed to by Applicant in the specification do not provide sufficient data to enable these proposed uses, as discussed above. "Tossing out the mere germ of an idea does not constitute enabling disclosure... [R]easonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech, Inc. v. Novo Nordisk Inc.*, 108 F.3d 1361, 1366, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997).

Claims 1, 6, 34, 61-67 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth in item 11 of Paper 12.

Citing case law, Applicant argues that the claims have been amended to set forth both structural and functional features, e.g. that the encoded polypeptide has GPCR activity and that it have a certain percent identity to the wild-type polypeptide. This argument has been fully considered but not deemed persuasive. As stated before, regarding variants of the polypeptide, there is no asserted correlation between any particular structure and any particular function. A percent identity provides for no particular structure at all, it is simply a statistic about which a given protein is allowed to deviate from a reference protein. It provides absolutely no information as to any particular amino acid sequence, nor to the maintenance or gain of any particular function. Contrary to Applicant's assertions, percent identity provides absolutely no commonly shared structural features between any two nucleic acids nor any two proteins. Thus, the skilled artisan readily appreciates that simply verbalizing that a protein should have some percent sequence identity with another protein and that it should also have some particular function, in no way places one in possession of this protein.

Applicant argues that the examiner's reasoning conclusory and is not supported by the MPEP or case law e.g. regarding *Lilly* and *Amgen* as analyzed by Applicant. This argument has been fully considered but not deemed persuasive. Regarding *Lilly*, percent identity provides no particular structural feature "that is common to the members of the genus". Regarding *Amgen*, there is no "particular known structure" in which the "function is sufficiently correlated".

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX months.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



July 6, 2006



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER